

Serial No.: 10/047,079
Group Art Unit: 3762
Examiner: L. Deak
Atty. Docket No.: 22719-26

REMARKS

The present Office Action addresses and rejects claims 3 and 5-20.

Amendments to the Claims

Applicants amend claim 19 to recite that the coil-shaped region has an outer diameter, measured across the coil-shaped region, that is substantially equal to an outer diameter of the catheter. This limitation is similar to the limitation previously added to independent claim 3, and it is merely added to expedite prosecution. Applicants do not believe that this limitation is necessary to distinguish over the art of record.

Claim Rejections

Claims 3 and 5-20 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,141,502 of Macaluso, Jr. ("Macaluso") in view of U.S. patent No. 5,209,723 of Twardowski et al. ("Twardowski"). The Examiner argues that Macaluso discloses a catheter substantially as claimed, except the diameter of the coiled region being "substantially similar" to the diameter of the proximal portion of the catheter. Thus, the Examiner relies on Twardowski to disclose a fluid flow catheter having a distal end with a "helical shape that is slightly larger than the diameter of the catheter itself in order to prevent the openings in the catheter from engaging the surrounding tissue." The Examiner argues that "it would have been obvious to one of ordinary skill in the art at the time of [the] invention to form the helical portion of the catheter into a shape that is substantially similar to the diameter of the proximal portion of the catheter in order to ensure a proper fit [sic] of the catheter into the designated space while still preventing the catheter's engagement with surrounding tissue." July 12, 2005 Office Action, p. 3.

At the outset, Macaluso cannot be relied on to render the pending claims obvious, in view of *any* secondary reference, because there is no motivation to modify the coiled distal portion of Macaluso to have an outer diameter that is substantially the same as an outer diameter of the proximal portion of the catheter. In fact, such a modification is contrary to the teachings of Macaluso.

The Examiner argues that a person of ordinary skill in the art would be motivated to modify

Serial No.: 10/047,079
Group Art Unit: 3762
Examiner: L. Deak
Atty. Docket No.: 22719-26

the catheter of Macaluso to have a coiled shaped distal portion with an outer diameter, measured across the coil, that is substantially equal to an outer diameter of the proximal portion of the catheter "in order to ensure a proper fir [sic] of the catheter into the designated space while still preventing the catheter's engagement with surrounding tissue." This is incorrect. First, Macaluso already provides a distal portion that is configured to ensure a proper fit. As specifically stated at Col. 3, lines 50-51, the "double helix . . . registers tightly within the renal pelvis 12, as shown in FIG. 3." Second, a person of ordinary skill in the art would not be motivated to *prevent* the catheter's engagement with surrounding tissue. To the contrary, Macaluso teaches a "ureteral stent apparatus that solves the problems of stent migration by providing a substantially non-migratable stent apparatus . . ." Col. 1, lines 51-53. The distal portion is shaped to engage the tissue. Accordingly, the Examiner has failed to provide any motivation to make the suggested modification.

Not only would it not have been obvious to a person of ordinary skill in the art to modify Macaluso, as suggested by the Examiner, but such a modification would render the catheter useless for its intended purpose. The ureteral stent disclosed by Macaluso has a coiled distal portion that is specifically shaped to fit within a patient's bladder. If the coiled distal portion were modified to have a diameter, as measured across the coil, that is *substantially equal* to an outer diameter of the proximal portion of the catheter, the device would no longer function as a stent that fits within the patient's bladder. Rather, since the outer diameter of the device would be substantially constant along the entire length thereof, the device would migrate from the implant site. This is specifically contrary to the problem to be solved by Macaluso, as stated above.

While the above reasons are more than sufficient to overcome the pending rejection and to eliminate Macaluso as 103(a) prior art, Applicant's further note that Twardowski does not remedy the deficiencies of Macaluso. In fact, Twardowski is merely cumulative of Macaluso. Twardowski fails to teach or even suggest a catheter having a coiled distal portion with an outer diameter that is *substantially equal* to an outer diameter of a proximal portion of the catheter. As quoted by the Examiner, and as specifically stated in Twardowski, the catheter has a helical distal portion, "the helical shape being of a diameter *slightly larger* than the catheter diameter . . ." Col. 4, line 67 to Col. 5, line 1. Twardowski further states that the larger diameter of the helical portions prevents the second port (26), which is formed proximal to the helical portion, from engaging the walls when

Serial No.: 10/047,079
Group Art Unit: 3762
Examiner: L. Deak
Atty. Docket No.: 22719-26

fluid is being suctioned therethrough. See Col. 5, lines 1-3. In other words, the distal portion is formed into a helical configuration to prevent the port from engaging the walls. Twardowski does not teach or even suggest forming the distal portion from a smaller diameter catheter which would allow the distal portion to be wound into a coil that has an outer diameter, measured across the coil, that is equal to the diameter of the proximal portion of the catheter, as required by claim 3. To the contrary, it appears that the catheter of Twardowski, like Macaluso, has a substantially *constant* outer diameter along a length thereof, and that the distal portion is merely wound into a coil to increase the outer diameter at the distal end. Accordingly, Twardowski does not remedy the deficiencies of Macaluso.

Independent claims 3 and 19 therefore distinguishes over the cited references and represents allowable subject matter. Claims 5-18 and 20 are allowable at least because they depend from an allowable base claim.

Conclusion

Applicants submit that claims 3 and 5-20 are in condition for allowance, and allowance thereof is respectfully requested. Applicants encourage the Examiner to telephone the undersigned upon receipt of this response to discuss any issues that may remain.

Respectfully submitted,

Date: October 5, 2005


Lisa J. Michaud, Reg. No. 44,238
Attorney for Applicant(s)

NUTTER, MCCLENNEN & FISH, LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA 02210-2604
Tel: (617)439-2550
Fax: (617)310-9550

1468126.1